K120888

## 510(k) Summary

NOV 9 2012

**Company Name:** Nihon Kohden Corporation
90 Icon Street
Foothill Ranch, CA 92610

**Device Name:** Nihon Kohden PSG-1100 Sleep Diagnostic System

**510(k) Sponsor, Contact:** Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Steve Geerdes
Director Quality Assurance and Regulatory Affairs
Phone: (949) 580-1555 Ext. 3325
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**Summary Date:** Revised 11/7/2012

**Common Name:** Electroencephalograph amplifier (EEG Amplifier)

**Classification Names:**

| | | |
|---|---|---|
| Electroencephalograph | 882.1400 | GWQ |
| Standard Polysomnograph with Electroencephalograph | 882.1400 | OLV |

**Predicate Device**

| | |
|---|---|
| Nihon Kohden JE-912A PSG Input Box | K022121 |

Additional predicates

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| Nihon Kohden EEG-1200A Series Neurofax | K080546 |
| Nihon Kohden JE-921A junction Box | K050833 |
| Neurotronics Polysmith | K062943 |

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## 1.0 Description of Device

The PSG-1100 Sleep Diagnostic System is a digital PSG amplifier intended to record the electrical activity of the brain (EEG) and other bio-potential signals and to record physiological data required for sleep studies.

The device consists of an amplifier box (head box) and main interface unit. The head box operates with commercially available sensors and interfaces with a main unit which connects to and communicates with computer hardware/ software via Ethernet connection.

## 2.0 Intended Use of Device

The PSG-1100 Sleep Diagnostic System is intended to record the physiological data required for EEG and sleep studies (Polysomnography or PSG). These data may be used by clinicians in Sleep Disorders, Epilepsies and other disorders as a diagnostic aid. This device is intended for use by medical personnel and will be available for use within a medical facility or outside of a medical facility under direct supervision of a medical professional.

## 3.0 Technical Characteristics

The PSG-1100 head box provides the $SpO_2$ capability of monitoring through $SpO_2$ probe, internal module is a standard feature. $ETCO_2$ is an optional feature and can be added via TG-970P or TG-920P $ETCO_2$ module. Airflow monitoring can be measured through the internal pressure transducer by connecting commercially available filtered airflow cannulas via the built in luer lock connector. As with the existing device, the operator performs an impedance check and runs the calibration program. Electrodes and/or sensors are attached to the patient and connect to the corresponding jacks on the junction box, which is optically isolated via the main unit to ensure electrical safety. Skin-electrode impedance check is performed to verify surface electrode connection and impedance levels. The operator then begins recording waveform data.

The analog bio-potential signals applied to the electrode junction box are digitized. The DSP (digital signal processor) in combination with the device software reproduces the waveforms.

Technical comparison

| | New PSG-1100A | JE-921A<br><br>Junction Box | PSG Input Box<br><br>JE-912A |
|---|---|---|---|

| | | K050833/080546 | K022121 |
|---|---|---|---|
| Number of Channels(*) | 42 | 32 | 34 |
| Input Impedance | 100 M ohm | 100 M ohm | 100 M ohm |
| Calibration Check | Step square<br>50 uV (1 step) | Step square or Sine wave<br>2 to 1000 uV (9 steps) | Step square or Sine wave<br>2 to 1000 uV (9 steps) |
| Impedance Check | All inputs with Screen and Input box readout | All inputs with Screen and Input box readout | All inputs with Screen and Input box readout |
| Common-Mode Rejection Ratio (CMRR) | 105 dB or more | 105 dB or more | 105 dB or more |
| Noise Level | < 1.5 uV p-p (0.53 to 60 Hz) | < 1.5 uV p-p (0.53 to 60 Hz) | < 1.5 uV p-p (0.53 to 60 Hz) |
| Frequency Response | 0.08 to 300 Hz | 0.08 to 300 Hz | 0.08 to 120 Hz |
| High-pass Filter (Low-cut) | 0.08 to 53 Hz<br>DC standard | 0.016 to 159 Hz<br>DC standard | 0.016 to 159 Hz<br>DC standard |
| Low-pass Filter (High-cut) | 15 to 300 Hz | 15 to 300 Hz | 15 to 120 Hz |
| AC Filter | 50 or 60 Hz (rejection ratio > 1/25) | 50 or 60 Hz (rejection ratio > 1/25) | 50 or 60 Hz (rejection ratio > 1/25) |
| Sensitivity | OFF, 0.1 to 200 uV/mm (20 steps)<br>DC: OFF, 10 to 200 mV/mm (10 steps) | OFF, 1 to 200 uV/mm (15 steps)<br>DC: OFF, 10 to 200 mV/mm (10 steps) | OFF, 1 to 200 uV/mm (15 steps)<br>DC: OFF, 10 to 200 mV/mm (10 steps) |
| A-D Conversion | 16 bits | 16 bits | 16 bits |

| | | | |
|---|---|---|---|
| Sampling | All channels<br>200, 250, 500, 1000, 2000 Hz | All channels<br>100, 200, 500, 1000 Hz | All channels<br>100, 200, 500 Hz |
| Display<br>Resolution<br>Channels | <br>1600 x 1200<br>32 | <br>1600 x 1200<br>64 + Mark Channel | N/A |
| Power | 100-240 V +/- 10%<br>50 / 60 Hz<br>42 VA (Main unit only) | 120 V +/- 10%<br>50 / 60 Hz<br>750 VA (including PC and display) | N/A |
| Operating Environment | Temperature: 10 to 35 degree C<br>Humidity: 30 to 80 % | Temperature: 10 to 35 degree C<br>Humidity: 30 to 80 % | Temperature: 10 to 35 degree C |

## 4.0 Data Summary

Testing of the Nihon Kohden the PSG-1100A was performed in compliance with Nihon Kohden Corporation design control process. The testing showed PSG-1100A met equivalent acceptance criteria as the predicate devices and was shown to be equivalent in safety and effectiveness to the predicate devices
Testing included:

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| User needs / Intended use/Functional | Confirmed by verification/validation testing in compliance with the Design Control requirements. User need and intended use was shown to be equivalent in safety and effectiveness to the predicate devices. The modifications do not alter the fundamental scientific technology of the device |

| | |
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| Chassis | Confirmed by verification/validation testing in compliance with the Design Control requirements. The Chassis was shown to be equivalent to the predicate devices |
| Labeling | Confirmed by verification/validation testing in compliance with the Design Control requirements. Labeling was shown to be equivalent to the predicate devices |
| Operating environment [temperature and humidity, EMC and EMI] | Confirmed by verification/validation testing in compliance with the Design Control requirements. The Operating environment was shown to be equivalent to the predicate devices |
| Storage environment | Confirmed by verification/validation testing in compliance with the Design Control requirements. Storage environment was shown to be equivalent to the predicate devices |
| Condition for transport | Confirmed by verification/validation testing in compliance with the Design Control requirements. Codition of transport was shown to be equivalent in safety and effectiveness to the predicate devices |
| Risk analysis | Based on risk analysis the new device was shown to be equivalent in safety and effectiveness to the predicate devices no new questions were raised. |

The device is in compliance with the following voluntary industrial standards:

Medical Electrical Equipment

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|---|---|
| IEC 60601-1 | Part1: General requirements for safety 1998-12 |
| IEC 60601-1, Amendment 1 | Part 1: General Requirements for safety, Amendment 1, 1991-11 |
| IEC 60601-1, Amendment 2 | Part 1: General Requirements for safety, Amendment 2, 1995-03 |

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| IEC 60601-1-1 2nd edition | Part 1-1: General requirements for safety – Collateral standard. Safety requirements for medical electrical systems, 2000-12 |
| IEC 60601-1-2 2nd edition | Part 1-2: General requirements for safety – Collateral standard. Electromagnetic compatibility, 2001-09 |
| IEC 60601-1-2 2nd edition, Amendment 1 | Part 1-2: General requirements for safety – Collateral standard. Electromagnetic compatibility. Amendment 1, 2004 |
| IEC 60601-2-26 | Part 2-26: Particular Requirements for the safety of electroencephalographs, 2002-11 |
| CAN/CSA-C22.2 No. 601.1-M90 | Medical electrical equipment, Part 1: General requirements for safety. |
| CAN/CSA-C22.2 No. 601.1S1-94 | Supplement No. 1-94 to CAN/CSA-C22.2 No. 601-1-M90 Medical Equipment- Part 1:General requirements for safety. |
| CAN/CSA-C22.2 No. 601.1B-90 | Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 Medical equipment Part 1: General requirements for safety: 2002 |
| CAN/CSA-C22.2 No. 60601-1-1-02 | Medical electrical equipment, Part 1-1: General requirements for safety- Collateral: Safety requirements for medical electrical systems, 2006 |
| CAN/CSA-C22.2 No.60601-1-2-03 | Medical Electrical Equipment . Part 1-2: General Requirements for Safety . Collateral Standard: Electromagnetic Compatibility . Requirements and Tests (Adopted IEC 60601-1-2:2001, second edition, 2001-09) |
| CAN/CSA C22.2 60601-2-26-04 | Medical Electrical Equipment part 2-26: Particular requirements for the safety of Electroencephalographs, adopted IEC 60601-2-26 Ed.2 (02). |

## 5.0 Conclusions

Based on the comparison information in the technical comparison chart above and confirmed by verification/validation testing in compliance with the Design Control requirements. The intended use and fundamental scientific technology of the device (Nihon Kohden PSG-1100 Sleep Diagnostic System) was shown to be equivalent in safety and effectiveness to the predicate devices, JE-912A PSG Input Box k022121 and the JE-921A Junction Box k050833/k080546, No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Nihon Kohden America, Inc.
c/o Mr. Steve Geerdes
90 Icon Street
Foothill Ranch, CA 92610

NOV 9 2012

Re: K120888
Trade/Device Name: PSG-1100 Sleep Diagnostic System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV
Dated: September 6, 2012
Received: September 7, 2012

Dear Mr. Geerdes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and
Physical Medicine
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if known): __k120888__

Device Name: PSG-1100 Sleep Diagnostic System

Indications for Use:

The PSG-1100 Sleep Diagnostic System is intended to record the physiological data required for EEG and sleep studies (Polysomnography or PSG). These data may be used by clinicians in Sleep Disorders, Epilepsies and other disorders as a diagnostic aid. This device is intended for use by medical personnel and will be available for use within a medical facility or outside of a medical facility under direct supervision of a medical professional.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

KRISTEN BOWSHER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120888